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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,555	03/29/2005	Flemming Madsen	P70463US0	7874

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EXAMINER	
BERMAN, SUSAN W	
ART UNIT	PAPER NUMBER
1711	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,555	MADSEN ET AL.	
	Examiner	Art Unit	
	Susan W. Berman	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 01/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

Claim 4 is objected to because of the following informalities: "polyethyleneglycol (PEG)" appears in both lines 6 and 7. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is intended to be claimed in the recitation "PVP based copolymers". Specifically, it is not clear what is intended by the term "based" in "PVP based". If applicant intends to claim copolymers of PVP, it should be so stated. Regarding claim 6, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al [US 2001/0044482 A1] in view of Sawhney et al (5,844,016).

Hu et al disclose IPN compositions for forming hydrophilic hydrogel contact lenses comprising polymerizable monomers and crosslinking agent and a soluble hydrophilic IPN agent, such as polyvinylpyrrolidone, a photoinitiator and/or a thermal initiator. The crosslinker is preferably polyethylene glycol dimethacrylate [0044]. Free radical thermal initiators and photoinitiators are taught for use alone or in combination, such as azo and peroxide compounds and phenyl ketone photoinitiators [0047]. Peroxydisulfate initiators are not mentioned.

Sawhney et al teach a polymer gel obtained by photopolymerization of acrylated PEG in the presence of a combination of chemical initiators and photochemical initiators. The chemical initiators disclosed include potassium persulfate, ammonium persulfate, peroxygen compounds such as hydrogen peroxide and redox catalyst with a transition metal (column 5, lines 38, to column 6, line 56). Sawhney et al teach that a very slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution (column 6, lines 46-52) See Examples 11, 12 and 22. Sawhney et al teach polymerization by irradiation of acrylated PEG in aqueous solution and in the presence of a photoinitiator, an organic peroxide such as hydrogen peroxide, and a ferrous ion. Sawhney et al teach polymerizing monomers to form a surface coating that appears to be a graft polymerization on the surface, such as a tissue surface. Example 10 discloses a solution comprising polyethylene glycol 400 and an acrylated PEG crosslinking monomer.

It would have been obvious to one skilled in the art at the time of the invention to substitute the initiator system taught by Sawhney et al for the initiator system in the method disclosed by Hu et al. Hu et al provide motivation by teaching that peroxide initiators are useful. Sawhney et al provide motivation by teaching persulfates as well as peroxygen compounds such

as hydrogen peroxide are suitable initiators in an analogous polymerization method. Sawhney et al also teach that a slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution in the presence of the metal ions. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of taking advantage of the benefits of providing an initiator comprising a photoinitiator, an organic peroxide and ferrous ions to speed up the polymerization, as taught by Sawhney et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bamford et al (5,618,887) disclose functionalization of polymers using peroxydisulphate in an aqueous medium followed by grafting with mono-functional monomers (column 1, line 54, to column 2, line 10, and column 3, line 64, to column 4, line 13). The disclosed polymers include nylons and poly(glycols) and vinyl polymers (column 2, line 61, to column 3, line 18). Grafting vinyl monomers by free radical reactions using conventional ceric ion technique is taught (column 4, lines 26-36). Bamford et al do not teach irradiation.

Boschetti (4,189,370) discloses a process for obtaining gels by radical polymerization in aqueous solution of N-methylol acrylamide and a bifunctional allylic or acrylic compound resulting in crosslinking. Boschetti teaches peroxide catalysts and/or ultraviolet radiation. Addition of polysaccharides is taught. See column 2, lines 11-59. N,N,N',N'-tetramethylethylenediamine-ammonium persulphate and N,N,N,',N'-

tetramethylethylenediamine-riboflavine-hydrogen peroxide-UV are examples of the catalytic system (column 2, lines 40-44 and Example 1). Example 4 teaches UV radiation with hydrogen peroxide in the catalyst system. Boschetti does not teach one or more hydrophilic polymers in the solution.

Mayhan et al (4,589,964) disclose a process for graft polymerization by peroxidizing the surface of a substrate and graft polymerizing an ethylenic monomer to the substrate in the presence of metal ions. Mayhan et al teach various polymeric substrates in column 3, lines 8-14. The mechanism of free radical graft polymerization is taught in column 3, line 28, to column 4, line 20.

Kim et al, in the article "Albumin Release from Biodegradable Hydrogels Composed of Dextran and Poly(Ethylene Glycol) Macromer", disclose photopolymerization of hydrogels in the presence of ammonium peroxydisulfate and PEGDMA crosslinker. The difference from the instantly claimed method is that the hydrogel polymer disclosed is a saturated dextran polymer having (meth)acrylate functional groups. The phrase "wherein the hydrophilic polymer are saturated" in the instant claims 1 and 9 distinguishes the instantly claimed method from the disclosure of Kim et al.

Alberts et al (4,056,671) disclose a process for preparing styrene acrylonitrile copolymers in the presence of a radical former. Alberts et al teach radicals produced by photoreactions in the presence of peroxides as polymerization catalysts and that ammonium and potassium peroxydisulphate are preferred water soluble initiators and that heavy metal salts may be added as reducing agents in redox systems (column 2, line 53, to column 3, line 5). Examples 1 and 2 disclose peroxydisulphate catalysts in thermal polymerizations. Example 6 employs

polyvinylalcohol dispersing agent and thermal polymerization. Polymerization in aqueous suspension comprising polymeric dispersing agents is taught (column 3, lines 16-30, and column 4, lines 34-40). The differences are that Alberts et al teach preparation of porous bead polymers rather than a hydrogel and that graft polymerization using a crosslinker is not mentioned.

Chmelir et al (5,340,853) disclose polymer-based swelling and absorbing agents for water, aqueous solutions and body liquids. Component A is a water-swellable polymer gel or copolymer gel crosslinked with a polyfunctional compound. Polymers and cross-linking monomers are taught in column 3, line 60, to column 4, line 49. Chmelir et al teach that polymerization can be by chemical catalysis and/or high-energy radiation/light. Peroxydisulphate compounds and mixtures of photoinitiators and peroxide-containing catalyst systems are taught (column 4, line 50, to column 5, line 3). Examples 15-17 teach polymerization of acrylic acid in the presence of a crosslinking monomer using a mixture of benzil dimethyl ketal and sodium peroxidisulfate to produce a polymer gel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Berman

SB
4/14/07

Susan W Berman
Primary Examiner
Art Unit 1711